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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,399	07/25/2003	Manne Satyanarayana Reddy	BULK 3.0-021	2853

45776 7590 09/15/2005

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EXAMINER
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SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/627,399

**Applicant(s)**

REDDY ET AL.

**Examiner**

Robert Shiao

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 07/20/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-18 is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This application claims benefit of the foreign application, INDIA 594/MAS/2002 with a filing date 08/12/1999. A certified copy of the priority document has been filed. Therefore, the foreign priority has been granted.
2. Amendment of claims 2-10 in the amendment filed July 20, 2005, is acknowledged. Claims 1-18 are pending in the application.

### ***Responses to Amendment/Arguments***

3. Applicant's arguments regarding rejection of claim 2 under 35 U.S.C. 112, second paragraph, filed on July 20, 2005, have been fully considered but they are not persuasive. Applicants also cites a case law , i.e., *Ex parte Lewin*, 154 U.S.P.Q. 487 (P.O.Bd App. 1966), is also acknowledged. However, the instant X-ray powder diffraction data has not been incorporated, therefore, rejection of claim 2 under 35 U.S.C. 112, second paragraph, is maintained.
4. Applicant's arguments regarding rejection of claims 1-18 under 35 U.S.C. 103(a), filed on July 20, 2005, have been fully considered and they are not persuasive, in part. A number of case laws cited by applicants, i.e., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) or *Ex parte Clapp*, 227 USPQ 972.973 (Bd.PatApp. &Interf.1985), are also acknowledged.

It is noted that it has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of amorphous or crystals to secure a pure and stable product. There is no patentable distinction in the concept of a chemical

compound in amorphous or crystalline form over the same compound, i.e., Winterbornet al. compounds, see *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966).

The motivation to make the claimed an amorphous form of known pharmaceutically useful compounds derives from the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc. Therefore, absent a showing of unobvious and superior properties, the instant claimed amorphous forms of known compounds would have been suggested to one skilled in the art. Therefore, rejection of claims 1-2 under 35 U.S.C. 103(a) over Winterbornet al. EP 0496307 A1 in view of Crisp et al. US 4,820,833 or Cheronis's publication, "Semimicro Experimental Organic Chemistry", 1958, Chapter 5, is maintained.

5. Claim 3-18 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to processes of preparing amorphous form of sumatriptan succinate.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Telephone Inquiry***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1626

  
TAOFIQ SOLOLA  
PRIMARY EXAMINER

  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626

  
Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

September 12, 2005